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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/541,429 | 03/14/2006 | Alessio Moriconi | 3765-0116PUS1 | 6234 |

2292 7590 08/05/2008

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| EXAMINER | |
|---|---|
| NOLAN, JASON MICHAEL | |
| **ART UNIT** | **PAPER NUMBER** |
| 1626 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 08/05/2008 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/541,429 | MORICONI ET AL. | |
| | Examiner | Art Unit | |
| | JASON M. NOLAN | 1626 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *27 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 11-15* is/are rejected.

7)☒ Claim(s) *10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/5/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

This Office Action is responsive to Applicants response to Notice of Non-Compliant Amendment, filed 03/27/2008. Claims 1-15 are pending in the instant application; of which Claims 6, 12, 13, & 15 are currently amended.

### *Information Disclosure Statement*

Applicants' information disclosure statement (IDS), filed on 07/05/2005 has been considered. Please refer to Applicants' copy of the 1449 submitted herein.

### *Claim Rejections - 35 USC §§ 101 & 112*

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 & 15 provide for the *use of* compounds of the formula I, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-7 & 15 are rejected under 35 U.S.C. § 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an

improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. § 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 7, 8, 14 & 15 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 7 & 8 recite the language “derivatives” and the scope of this term is unclear, such that it fails to define the metes and bounds of its limitation. The term “derivatives” includes, among other things, isomers of the compounds according to Formula (I). Isomers are only required to have the same elements and ratios thereof, and therefore may or may not resemble the depicted structure of formula (I). For this reason, a comprehensive search cannot be made on the indefinite formula (I) because there are infinite combinations of elements in the generic formula (I).

Claims 1 & 8 recite the language “including” in the definition of Hy and the scope of this term is unclear, such that it fails to define the metes and bounds of its limitation. For this reason, the scope of Hy is indefinite as it may or may not include other limitations besides the recited methyl, ethyl, chlorine, etc.

Claims 14 & 15 recite the language “damages caused by ischemia and reperfusion” and the scope of this term is unclear, such that it fails to define the metes and bounds of its limitation. There is no guidance to what is included or excluded from the term 'damages,' nor is there any guidance as to determine that the “damages” were in fact a result of ischemia or reperfusion.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 & 11-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, the compounds of formula I wherein **A** is any and/or all 5-6 membered aromatic or heteroaromatic ring systems, optionally fused with a second ring to give a bicyclic structure moiety. In contrast to Applicants preferred embodiments of formula I wherein **A** = phenyl, pyrrole, indole, and 7-aza-indole, there are no working examples or synthetic procedures that would convey to one of skill in the art that Applicant had possession of compounds according to formula I wherein **A** is not equal to phenyl, pyrrole, indole, or 7-aza-indole. For product claims, the claim limitations will

define discrete physical structures, and although the generic term aryl comprehends a limited number of species, the species are patentably distinct. Those skilled in the art would recognize that all of the compounds characterized in the instant application are drawn to formula (I) wherein **A** = phenyl, pyrrole, indole, and 7-aza-indole; therefore, such an element would be considered essential or critical for the utility of the products. For this reason, Applicant's specification has not reasonably conveyed to those skilled in the art that the Applicant was in possession of the entire scope for the claimed invention as of the date of the invention.

Claims 13-15 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while enabling for a method of *treatment* of ischemia or reperfusion, does not reasonably provide enablement for *prevention* of ischemia or reperfusion. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

*The nature of the invention*

The nature of the invention is compounds and compositions of Formula I, the process for preparing these compounds, and methods of using these compounds.

*The state of the prior art and the predictability or lack thereof in the art*

The state of the prior art, namely pharmacological art, involves screening *in vitro* and *in vivo* to determine if the compounds exhibit desired pharmacological activities, which are then tested for their efficacy on human beings. There is no absolute

predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face. The instant claimed invention is highly unpredictable as discussed below.

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the claimed invention is highly unpredictable since one skilled in the art would recognize that a group of compounds and compositions may provide a treatment for ischemia or reperfusion, but it does not mean that the same group of compounds and compositions may prevent ischemia or reperfusion.

*The amount of direction or guidance present and the presence or absence of working examples*

There is no direction or guidance provided which supports Applicant's claimed method for the prevention of ischemia or reperfusion as indicated. The direction or guidance present in Applicants' Specification for a method of using the compounds and compositions of Formula I to treat clinical conditions of ischemia or reperfusion is found on pages 14-17 of the specification.

*The breadth of the claims, quantity of experimentation, and level of skill in the art*

Claims 13-15 are drawn to "…use in the prevention or treatment…" In order to prevent a disease, one would need to precisely identify those subjects likely to acquire

such a disease, administer Applicant's claimed invention, and then demonstrate that if the identified subject did not develop the disease, such an effect was the direct result of administration of the claimed invention.

Because of the aforementioned reasons, a person of skill in the art could not practice the claimed invention herein, or a person of skill in the art could practice the claimed invention herein only with undue experimentation and with no assurance of success. Deleting the word "prevention" in Claims 13-15, (as well as the indefinite term "damages caused by") can overcome this rejection.

***Claim Objections***

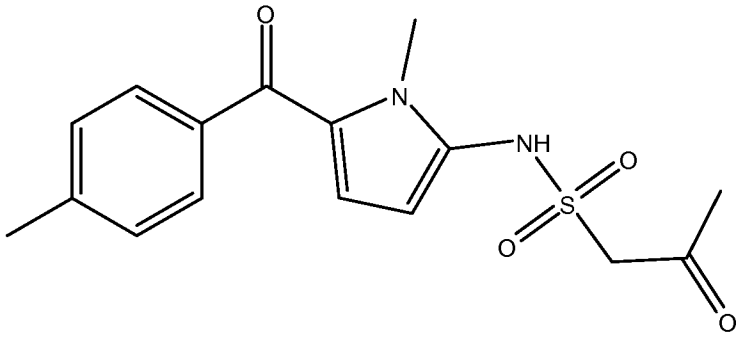
Claims 7 & 10 are objected to because of the following informalities: said claim recites a list of species which should be separated by a comma or semicolon wherein the last two species should be separated by a comma or semicolon and the word - - and - -. Appropriate correction is required.

Claim 8 is objected to because of the following informalities: the term "2-arylacetic acid compounds" is not depictive of the structure, which is not an acetic acid. Appropriate correction is required.

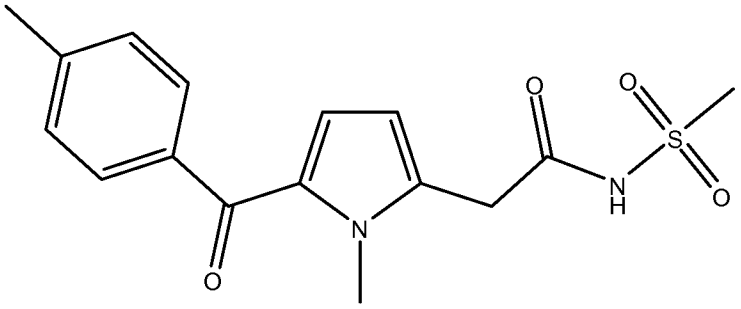
Claim 10 is objected to as being dependent upon a rejected base, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 10 is objected to because of the following informalities: the last species may be missing a space: -acetylmethanesulphonamide versus -acetyl methanesulphonamide. When typed into ChemDraw software, the two alternatives give two different structures, see below. Appropriate correction is required.

[1-methyl-5-(4-methylbenzoyl)-1H-pyrrol-2-yl]acetylmethanesulphonamide




[1-methyl-5-(4-methylbenzoyl)-1H-pyrrol-2-yl]acetyl methanesulphonamide



***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jason M. Nolan, Ph.D.** whose telephone number is **(571) 272-4356** and electronic mail is Jason.Nolan@uspto.gov. The examiner can normally be reached on Mon - Fri (9:00 - 5:30PM). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph M$^{c}$Kane** can be reached on **(571) 272-0699**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jason M. Nolan, Ph.D./

Examiner, Art Unit 1626

/Joseph K. McKane/

Supervisory Patent Examiner, Art Unit 1626